

*Handwritten signature/initials*

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/657418-Conf. #9018
	Filing Date	September 8, 2003
	First Named Inventor	Archibald I. BRAIN
	Art Unit	3743
	Examiner Name	Teena Kay Mitchell
Total Number of Pages in This Submission	Attorney Docket Number	0108195.00137US1

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment/Reply  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Reply to Missing Parts/Incomplete Application  <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____  <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard
<b>Remarks</b> 1. SB-08 (6 pp.) 2. 89 Publications		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	WILMER CUTLER PICKERING HALE AND DORR LLP		
Signature	<i>Richard A. Goldenberg</i>		
Printed name	Richard A. Goldenberg		
Date	Oct 3, 2005	Reg. No.	38,895

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Date: October 3, 2005 Signature: Tina M. Dougal (Tina M. Dougal)



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Dated: 10/3/05

Signature:

*Tina M. Dougal*  
(Tina M. Dougal)

Docket No.: 0108195.00137US1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Archibald I. BRAIN

Application No.: 10/657418

Confirmation No.: 9018

Filed: September 8, 2003

Art Unit: 3743

For: LARYNGEAL MASK AIRWAY DEVICE  
WITH POSITION CONTROLLING TAB

Examiner: Teena Kay Mitchell

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is being filed after the mailing date of the first Office Action on the merits and before the mailing date of a final Office Action or a Notice of Allowance.

Please charge the \$180.00 fee to our Deposit Account No. 08-0219.

Applicants request that the Examiner initial and return a copy of the enclosed Form PTO SB-08 with the next communication.

Dated:

OCT 3, 2005

Respectfully submitted,

*Richard A. Goldenberg*

By

Richard A. Goldenberg

Registration No.: 38,895

WILMER CUTLER PICKERING HALE AND  
DORR LLP

60 State Street

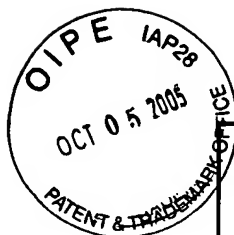
Boston, Massachusetts 02109

(617) 526-6000

Attorney for Applicant

10/06/2005 HDESTA1 00000048 080219 10657418

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<b>Effective on 12/08/2004.</b> <b>Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).</b>		<b>Complete if Known</b>	
<b>FEE TRANSMITTAL</b> <b>For FY 2005</b>		Application Number	10/657418-Conf. #9018
		Filing Date	September 8, 2003
		First Named Inventor	Archibald I. BRAIN
		Examiner Name	Teena Kay Mitchell
		Art Unit	3743
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Attorney Docket No.	0108195.00137US1
<b>TOTAL AMOUNT OF PAYMENT</b>	<b>(\$)</b> 180.00		

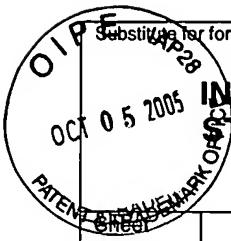
<b>METHOD OF PAYMENT</b> (check all that apply)	
<input type="checkbox"/> Check	<input type="checkbox"/> Credit Card
<input type="checkbox"/> Money Order	<input type="checkbox"/> None
<input type="checkbox"/> Other (please identify):	
<input checked="" type="checkbox"/> Deposit Account	Deposit Account Number: <u>08-0219</u> Deposit Account Name: <u>Wilmer Cutler Pickering Hale and Dorr LLP</u>
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)	
<input checked="" type="checkbox"/> Charge fee(s) indicated below	<input type="checkbox"/> Charge fee(s) indicated below, <b>except for the filing fee</b>
<input checked="" type="checkbox"/> Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17	<input checked="" type="checkbox"/> Credit any overpayments

<b>FEE CALCULATION</b>							
<b>1. BASIC FILING, SEARCH, AND EXAMINATION FEES</b>							
	<b>FILING FEES</b>		<b>SEARCH FEES</b>		<b>EXAMINATION FEES</b>		
		<b>Small Entity</b>		<b>Small Entity</b>		<b>Small Entity</b>	
<b>Application Type</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fee (\$)</b>	<b>Fees Paid (\$)</b>
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	
<b>2. EXCESS CLAIM FEES</b>							
<b>Fee Description</b>	<b>Fee (\$)</b>	<b>Small Entity Fee (\$)</b>					
Each claim over 20 (including Reissues)	50	25					
Each independent claim over 3 (including Reissues)	200	100					
Multiple dependent claims	360	180					
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>	<b>Multiple Dependent Claims</b>			
		x	=	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>				
		x	=				
<b>3. APPLICATION SIZE FEE</b>							
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
<b>Total Sheets</b>	<b>Extra Sheets</b>	<b>Number of each additional 50 or fraction thereof</b>	<b>Fee (\$)</b>	<b>Fee Paid (\$)</b>			
	- 100 =	/50	(round up to a whole number) x	=			
<b>4. OTHER FEE(S)</b>							
Non-English Specification, \$130 fee (no small entity discount)				<b>Fees Paid (\$)</b>			
Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement				180.00			

<b>SUBMITTED BY</b>			
Signature		Registration No. (Attorney/Agent)	38,895
Name (Print/Type)	Richard A. Goldenberg	Telephone	(617) 526-6000
		Date	Oct. 3, 2005

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Dated: <u>October 3, 2005</u>	Signature:  (Tina M. Dougal)

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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/657,418
Filing Date	September 8, 2003
First Named Inventor	Archibald I. J. Brain
Art Unit	3763
Examiner Name	Teena Kay Mitchell
Attorney Docket Number	108195.137US1 LMA-018

1

of

6

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US-RE 35,531	06/17/97	Callaghan et al.	
		US-Des 429,811	08/22/00	Bermudez	
		US-2,862,498	12/02/58	Weekes	
		US-3,554,673	01/12/71	Schwartz et al.	
		US-4,231,365	11/04/80	Scarberry	
		US-4,509,514	04/09/85	Brain	
		US-4,553,540	11/19/85	Straith	
		US-4,872,483	01/26/93	Shah	
		US-4,953,547	9/4/90	Poole, Jr.	
		US-4,995,388	02/26/91	Brain	
		US-5,038,766	08/13/91	Parker	
		US-5,241,956	09/07/93	Brain	
		US-5,249,571	10/05/93	Brain	
		US-5,282,464	02/01/94	Brain	
		US-5,297,547	03/29/94	Brain	
		US-5,303,697	04/19/94	Brain	
		US-5,339,805	08/23/94	Parker	
		US-5,339,808	8/23/94	Don Michael	
		US-5,355,879	10/18/94	Brain	
		US-5,391,248	02/21/95	Brain	
		US-5,529,582	06/25/96	Fukuhara	
		US-5,569,219	10/29/96	Hakki et al.	
		US-5,584,290	12/17/96	Brain	
		US-5,599,301	02/04/97	Jacobs et al.	
		US-5,623,921	04/29/97	Kinsinger et al.	
		US-5,632,271	05/27/97	Brain	
		US-5,653,229	08/05/97	Greenberg	
		US-5,655,528	08/12/97	Pagan	
		US-5,682,880	11/04/97	Brain	
		US-5,711,293	01/27/98	Brain	
		US-5,743,254	04/28/98	Parker	
		US-5,746,202	05/05/98	Pagan	
		US-5,771,889	06/30/98	Pagan	
		US-5,791,341	08/11/98	Bullard	
		US-5,850,832	12/22/98	Chu	
		US-5,865,176	02/02/99	O'Neil	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is established to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/657,418
				Filing Date	September 8, 2003
				First Named Inventor	Archibald I. J. Brain
				Art Unit	3763
				Examiner Name	Teena Kay Mitchell
Sheet	2	of	6	Attorney Docket Number	108195.137US1 LMA-018

		US-5,878,745	03/09/99	Brain	
		US-5,881,726	03/16/99	Neame	
		US-5,896,858	04/27/99	Brain	
		US-5,915,383	06/29/99	Pagan	
		US-5,937,860	8/17/99	Cook	
		US-5,979,445	11/09/99	Neame et al.	
		US-5,983,897	11/16/99	Pagan	
		US-5,988,167	11/23/99	Kamen	
		US-6,003,510	12/21/99	Anunta	
		US-6,003,514	12/21/99	Pagan	
		US-6,012,452	01/11/00	Pagan	
		US-6,021,779	02/08/00	Pagan	
		US-6,050,264	04/18/00	Greenfield	
		US-6,070,581	6/6/00	Augustine et al.	
		US-6,079,409	6/27/00	Brain	
		US-6,095,144	8/1/00	Pagan	
		US-6,116,243	09/12/00	Pagan	
		US-6,119,695	9/19/00	Augustine et al	
		US-6,390,093	5/21/02	Mongeon	

Examiner Signature		Date Considered	
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/657,418
				Filing Date	September 8, 2003
				First Named Inventor	Archibald I. J. Brain
				Art Unit	3763
				Examiner Name	Teena Kay Mitchell
Sheet	3	of	6	Attorney Docket Number	108195.137US1 LMA-018

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		2,012,750	08/24/99	Archibald I. J. Brain	
		2,067,782	06/15/99	Parker Medical Limited Partnership	
		0 294 200	04/15/92	Archibald I. J. Brain	
		0 389 272	09/26/90	Archibald I. J. Brain	
		0 402 872	12/19/90	L. Vad Technology, Inc.	
		0 580 385	05/08/96	Archibald I. J. Brain	
		0 712 638	05/22/96	Mallinckrodt Medical, Inc.	
		0 732 116	09/18/96	Smiths Industries Public Limited Company	
		0 796 631	09/24/97	Archibald I. J. Brain	
		0 845 276	06/03/98	Smiths Industries Public Limited Company	
		0 865 798	09/23/98	Smiths Industries Public Limited Company	
		0 922 465	06/16/99	Smiths Industries Public Limited Company	
		1 125 595	8/22/01	Smiths Industries PLC	
		GB 2111394	12/03/82	Archibald I. J. Brain	
		GB 2205499	06/05/87	Archibald I. J. Brain	
		GB 2317342	08/29/97	Smiths Industries Public Limited Company	
		GB 2317830	09/05/97	Smiths Industries Public Limited Company	
		GB 2318735	10/24/97	Smiths Industries Public Limited Company	
		GB 2319478	10/24/97	Smiths Industries Public Limited Company	
		GB 2359996	9/12/01	Smiths Industries Public Limited Company	
		2321854	01/08/98	Smiths Industries Public Limited Company	
		2323289	02/25/98	Smiths Industries Public Limited Company	
		2323290	03/03/98	Smiths Industries Public Limited Company	
		2323291	03/03/98	Smiths Industries Public Limited Company	
		2323292	03/09/98	Smiths Industries Public Limited Company	
		10118182	05/12/98	Smiths Industries Public Limited Company	
		10216233	08/18/98	Smiths Industries PLC	
		10263086	10/06/98	Smiths Industries PLC	

Examiner Signature	Date Considered
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				Application Number	10/657,418	
				Filing Date	September 8, 2003	
				First Named Inventor	Archibald I. J. Brain	
				Art Unit	3763	
				Examiner Name	Teena Kay Mitchell	
Sheet	4	of	6	Attorney Docket Number		108195.137US1 LMA-018

		10328303	12/15/98	Smiths Industries PLC	
		11128349	05/18/99	Smiths Industries PLC	
		11192304	07/21/99	Smiths Industries PLC	
		11206885	08/03/99	Smiths Industries PLC	
		10277156	10/20/98	Smiths Industries PLC	
		10314308	12/02/98	Smiths Industries PLC	
		10323391	12/08/98	Smiths Industries PLC	
		WO 91/03207	3/21/91	Boston Scientific Corporation	
		WO 91/07201	05/30/91	Jeffrey D. Parker	
		WO 91/12845	9/5/91	Smiths Industries Public Limited Company	
		WO 92/13587	08/20/92	Archibald I. J. Brain	
		WO 95/33506	12/14/95	Archibald I. J. Brain	
		WO 97/12640	04/10/97	Archibald I. J. Brain	
		WO 97/12641	04/10/97	Archibald I. J. Brain	
		WO 98/16273	04/23/98	Augustine Medical Inc.	
		WO 99/06093	02/11/99	Garry Nimmo	
		WO 00/22985	04/27/00	Children's Hospital Inc.	
		WO 00/23135	04/27/00	K. Dimitriou	
		WO 00/61212	10/19/00	Vital Signs, Inc.	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/657,418
				Filing Date	September 8, 2003
				First Named Inventor	Archibald I. J. Brain
				Art Unit	3763
				Examiner Name	Teena Kay Mitchell
Sheet	5	of	6	Attorney Docket Number	108195.137US1 LMA-018

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, volume-issue number(s), page(s), publisher, city and/or country where published.	T <sup>2</sup>
	A1	Abdelatti, "A cuff pressure controller for tracheal tubes and laryngeal mask airway," <u>Anaesthesia</u> , 1999, 54 pp. 981-986	
	A2	Benumof J.L. "Management of the difficult airway with special emphasis on awake tracheal intubation," <u>Anesthesiol.</u> 1991. 75;6:1087.	
	A3	Benumof, "Laryngeal Mask Airway and the ASA Difficult Airway Algorithm," <u>Anesthesiology</u> 1996:v84 no.3:686-99	
	A4	Bernhard, et al., "Adjustment of Intracuff Pressure to Prevent Aspiration," <u>Anesthesiology</u> v. 50 no. 4:363-366, 1979	
	A5	Bernhard, et al., "Physical Characteristics of and Rates of Nitrous Oxide Diffusion into Tracheal Tube Cuffs," <u>Anesthesiology</u> 48:413-417 1978	
	A6	Brain, "The Laryngeal Mask - A New Concept in Airway Management," <u>Br. J. Anesth.</u> (1983), Vol. 55, pgs. 801-805	
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	A11	Brimacombe, "The split laryngeal mask airway," p. 639	
	A12	Broderick, "The laryngeal mask airway," (1989) <u>Anaesthesia</u> , Vol. 44, pgs. 238-241	
	A13	Burgard, et al., "The Effect of Laryngeal Mask Cuff Pressure on Postoperative Sore Throat Incidence," <u>J. of Clinical Anesthesia</u> 8:198-201, 1996	
	A14	Caplan R.A., Posner K.L., Wend R.J., Cheney F.W., "Adverse respiratory events in anesthesia: a closed claims analysis," <u>Anesthesiol.</u> 1990. 72:828-833.	
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	A20	Engbers, "Practical use of 'Diprifusor' systems", <u>Anaesthesia</u> 1998, 53, Suppl. 1, pp. 28-34	

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				Application Number	10/657,418
				Filing Date	September 8, 2003
				First Named Inventor	Archibald I. J. Brain
				Art Unit	3763
				Examiner Name	Teena Kay Mitchell
Sheet	6	of	6	Attorney Docket Number	108195.137US1 LMA-018

A21	Eriksson, et al., "Functional Assessment of the Pharynx at Rest and during Swallowing in Partially Paralyzed Humans," <u>Anesthesiology</u> Vol. 87, No. 5, Nov. 1997, pp. 1035-1042	
A22	Glen, "The development of 'Diprifusor': a TCI system for propofol," <u>Anaesthesia</u> 1998, 53, Suppl. 1, pp. 13-21	
A23	Gray et al., "Development of the technology for 'Diprifusor' TCI systems," <u>Anaesthesia</u> 1998, 53, Suppl. 1, pp. 22-27	
A24	Heath, "Endotracheal intubation through the Laryngeal Mask - helpful when laryngoscopy is difficult or dangerous," <u>European Journal of Anaesthesiology</u> 1991, Suppl. 4, 41-45	
A25	Hickey, et al., "Cardiovascular response to insertion of Brain's laryngeal mask," <u>Anesth. Corresp.</u> 1990, Vol. 45 pgs. 629-633	
A26	Inomata, et al., "Transient Bilateral Vocal Cord Paralysis after Insertion of a Laryngeal Mask Airway," <u>Anesthesiology</u> , 82:787-788, 1995	
A27	Jacobson et al., "A Study of Intracuff Pressure Measurements, Trends and Behaviours in Patients During Prolonged Periods of Tracheal Intubation," <u>Br. J. Anaesth.</u> 1981, 53, 97	
A28	Kambic, et al., "Intubation Lesions of the Larynx," <u>Br. J. Anaesth.</u> 1978, 50, 587-590	
A29	Kapila A., Addy E.V., Verghese C., Brain A.J., "Intubating LMA: a preliminary assessment of performance", <u>British Journal of Anaesthesia</u> , 1995; 75:228-229 (Abstract).	
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A36	Pennant, "Comparison of the Endotracheal Tube and Laryngeal Mask in Airway Management by Paramedical Personnel," <u>Anesth Analg</u> 1992:74:531-4	
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